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The Director-General of the World Health Organization presents his compliments and, pursuant to Resolution WHA23.50 of the Twenty-third World Health Assembly on Health Hazards of Food Additives, has the honour to transmit the following information on food additives which he has received under provision (2) of this Resolution. (The original communication from which this information is drawn is retained in the archives of WHO for consultation.)

The World Health Organization has been informed by the Director General of the Food Directorate, Health Protection Branch, Health and Welfare, Canada of the action taken in relation to the banning of the artificial sweetener saccharin by the following cable:

"Canadian Position on Saccharin

Ottawa - National Health and Welfare Minister Marc Lalonde today announced that following careful evaluation of all scientific evidence and after consultation with experts in other countries, the health protection branch (HPB) of his department is banning the artificial sweetener saccharin from use in foods, cosmetics and as a sweetening agent in drug preparations. This action is predicated on the results of a study that has been in progress for over three years in HPB laboratories, which indicate that saccharin is a potential cancer-causing agent.

Saccharin will be phased out in the following way, taking into account the amount of saccharin normally consumed in each product category:

1. The sale of beverages such as soft drinks, beverage bases and beverage mixes containing saccharin will not be permitted after July 1, 1977,
2. The sale of all other foods containing saccharin will not be permitted after November 1, 1977. It is proposed, in conjunction with medical experts and the food industry to review and assess the role of saccharin in special foods for diabetics. Exemptions from the ban will be considered upon receipt of their recommendations from these experts.
3. The sale of drugs containing saccharin as a non-medicinal ingredient will not be permitted after December 31, 1978. It is proposed through consultations with medical experts to review and assess the role of saccharin as a sweetener to obtain patient compliance with the direction for use of life-saving drugs. Exemptions to the ban will be considered upon receipt of recommendations from these experts.
4. The sale of cosmetics containing saccharin and which are subject to very limited ingestion, such as mouthwashes and toothpaste, will not be permitted after December 31, 1979.

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5. The sale of saccharin as a single ingredient drug or in combination with cyclamates will be limited to pharmacies as of September 1, 1977, to provide diabetics and others who must restrict their intake of carbohydrates with access to a carbohydrate-free sweetening agent.

This Canadian action has been taken after consultation with the Canadian Medical Association and the Registrars of Pharmacy. As stated above, the action is based upon the findings of a study conducted by HPP, in which rats were fed a diet providing 2,500 milligrams per kilogram (mg/kg) of body weight per day of sodium saccharin for two generations. The parent generation male animals given saccharin developed both benign (non-cancerous) and malignant (cancerous) bladder tumors. In male rats of the second generation whose mothers received saccharin during pregnancy and lactation, the bladder tumors were mostly of the malignant type. The increased incidence of bladder tumors in the second generation may be attributable to exposure of the young before birth (in utero) as a result of maternal ingestion of saccharin.

It must be stressed that the dose used in this study exceeded average human exposure by at least 800 times, based on consumption of one 12-ounce bottle of "diet" soft drink per day. No cases of human cancer attributable to saccharin have been identified. Action to restrict the use of saccharin by the general public is being taken, however, as a precautionary measure, in the interest of prudence. This decision recognizes that saccharin may be of value for certain well-defined segments of the population such as diabetics.

Because the experimental evidence on the safety of saccharin has not been clear-cut until the present time, to our knowledge no country has moved previously to withdraw saccharin from the market. The bladder tumors observed in the Canadian study have been reviewed by an international committee of pathologists. Accordingly, the results, expressed as a consensus opinion, have been conveyed to health agencies of other countries for their consideration."